

# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/DK04/000877

International filing date: 16 December 2004 (16.12.2004)

Document type: Certified copy of priority document

Document details: Country/Office: DK  
Number: PA 2003 01904  
Filing date: 19 December 2003 (19.12.2003)

Date of receipt at the International Bureau: 07 February 2005 (07.02.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland  
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse



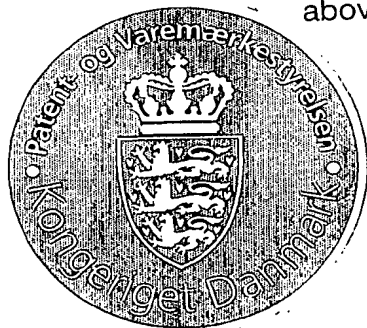
# Kongeriget Danmark

Patent application No.: PA 2003 01904  
Date of filing: 19 December 2003  
Applicant:  
(Name and address) Coloplast A/S  
Holtedam 1  
DK-3050 Humlebæk  
Denmark

Title: Klæbemiddel samt anvendelse af dette middel

IPC: C 09 J 153/02; A 61 L 15/58; C 09 J 7/02; C 09 J 125/10

This is to certify that the attached documents are exact copies of the above mentioned patent application as originally filed.



**Patent- og Varemærkestyrelsen**  
Økonomi- og Erhvervsministeriet

26 January 2005

*Susanne Morsing*  
Susanne Morsing

19 DEC. 2003

Modtaget

1

## **TITLE**

An Adhesive Composition and Use of Such Composition

## **BACKGROUND OF THE INVENTION**

### **5 1. Field of the Invention**

The present invention relates to pressure sensitive adhesive compositions suitable for various medical applications and especially suitable for use for adhesion to the skin. The adhesive composition may be used for securing ostomy appliances to the skin and for sealing around a stoma, for securing wound dressings or wound drainage bandages to the skin, for securing devices for collecting urine to the skin, or for securing orthoses or prostheses to the skin. More specifically, this invention relates to adhesive compositions comprising a rubbery elastomeric matrix comprising a block-copolymer and a homo-polymer, the use of such adhesive compositions for the preparation of a wound dressing or an adhesive wafer for an ostomy appliance, and to wound dressings or ostomy appliances comprising such adhesive composition.

### **2. Description of the Related Art**

Various skin adhesive agents are used today for the above-mentioned purposes.

A very widespread embodiment of skin adhesive agents comprises a self-adhesive elastomeric matrix, in which water absorbing, swelling particles, the so-called hydrocolloids, are dispersed.

Adhesive compositions comprising hydrocolloids have been known for many years. U.S. Patent No. 3,339,549 discloses a blend of a rubbery elastomer such as polyisobutylene and one or more water-soluble or water swellable hydrocolloids such as a powdery mixture of pectin, gelatine and carboxymethylcellulose. The adhesive mass has a water-insoluble film applied to one surface. A composition of this type is available commercially from E.R. Squibb & Sons Inc. under the trademark "Stomahesive" and is used as a skin barrier around stomas to prevent skin breakdown by the corrosive fluids discharged by the stoma.

In adhesive compositions of this type, the polyisobutylene is responsible for provision of the adhesive properties and the dispersed hydrocolloid powders absorb fluid and render the adhesive agent capable of also adhering to moist skin (wet tack). These compositions are also gaining increasing acceptance as wound dressings for dermal ulcers, burns and other exuding wounds.

One major problem which has been encountered with conventional adhesive compositions comprising hydrocolloids is their susceptibility to breakdown upon exposure to body fluids. When the compositions are used as skin barriers, e.g., around stomas, absorption of fluid is desirable, but excessive swelling causes the composition to lose its integrity, opening for leaks, and the barrier must be replaced more often than is desirable from a skin protection point of view, and very often, a residue remains on the skin, which in many cases is difficult to remove.

A number of attempts have been made to improve the properties of adhesive compositions in order to overcome the above-mentioned drawbacks.

In a number of embodiments, styrene copolymers have been incorporated which is disclosed in a number of patent references.

Thus, US Patent No. 4,231,369 Sorensen et al. disclose an ostomy skin barrier consisting of a styrene copolymer having dispersed therein a water-soluble hydrocolloid gum and a tackifier.

In US Patent No. 4,367,732 Poulsen et al. disclose an ostomy skin barrier consisting of a water soluble hydrocolloid dispersed in a continuous phase consisting of a styrene copolymer, a hydrocarbon tackifier, and a plasticizer, an antioxidant, and an oily extender.

US Patent No. 4,551,490 (Doyle et al.) discloses medical grade pressure sensitive adhesive compositions comprising a homogeneous mixture of 5-30% of one or more polyisobutylenes, 3-20% of one or more styrene radial or block type co-

polymers having a content of diblock copolymer below 20%, mineral oil, one or more water soluble hydrocolloid gums, and a tackifier. One or more water swella-  
ble cohesive strengthening agents, an antioxidant, and various other optional in-  
gredients also may be included within the adhesive composition.

5

US patent No. 5,492,943 discloses a pressure sensitive adhesive composition including a blend of two viscoelastic adhesive elastomers, specifically, high molecular weight polyisobutylene and a styrene block copolymer, which along with a plasticizer (preferably petrolatum) and a suitable tackifier and antioxidant, form a  
10 continuous phase in which hydrocolloids such as sodium carboxymethylcellulose and pectin are dispersed. The adhesive compositions disclosed in US patent No. 5,492,943 are stated to be used for wafers for adhering ostomy appliances to the skin and differ from known compositions by comprising styrene block-copolymers having a higher content of diblock copolymer, completely avoiding the use of low  
15 molecular weight polyisobutylene and furthermore by preferably not including gelatine.

WO 98/17329 discloses adhesive compositions comprising below 20% of styrene copolymer having a major content of diblock copolymer and furthermore comprising  
20 a tackifying liquid constituent.

Adhesives based on three-block styrene-isoprene-styrene (SIS) copolymers are highly elastic and show a very high degree of cohesion. Traditional SIS-based adhesives are all modified using a resin and plasticizer in order to obtain a suitable  
25 balance between the plastic and elastic properties in order to obtain satisfactory adhesiveness and, at the same time, sufficient plasticity which implies that the adhesive is able adapt to the structure and follow the movements of the skin without losing the grip.

30 In order to increase the softness, it is normal to use a considerable amount of plasticizer such as Dioctyl Adipate (DOA) or Dioctyl Phthalate (DOP). These plasticizers may leach out or migrate and come into contact with the skin or a wound

and cause adverse reactions, or migrate into the backing material causing performance and storage problems. Many plasticizers are claimed to have a negative impact on the health.

- 5 Lower molecular weight copolymers may be used as plasticizers or extenders. These may, however, cause cohesion problems within the adhesive leading to a too soft material with the tendency to cohesive break when peeled from the skin leaving residues on the skin.
- 10 Lower molecular weight homo-polymers of polyisobutylene or polybutylene can be used to modify the properties of SIS based adhesives. However, these homo-polymers are not fully compatible with the isoprene phase of the block copolymers they are intended to modify. Consequently, a multiphase polymer system is produced having rheological and mechanical properties being difficult to control
- 15 sufficiently for obtaining a satisfactory cohesion and suitable flowing properties.

Furthermore, SIS copolymers contain unsaturated chemical bonds and therefore are prone to yellowing and deterioration during processing due to exposure to radiation such as light or radiation sterilization and on long-term storage.

- 20 Loss or lack of cohesion, poor deterioration resistance when moisture has been absorbed combined with the risk of leaving residues on the skin are some of the greatest failings of current commercial medical adhesives.
- 25 Homo or di-block polymers of higher molecular weight can also be used for adhesive compositions. They are however more difficult to formulate to give a suitable balance of properties rendering the adhesive compositions suitable for use as medical pressure sensitive adhesives unless cross-linking can occur.
- 30 Styrene-isobutylene copolymers as such are known. They are known as random copolymers, which cannot form physically cross-linked domains as the styrene

blocks of a di, tri or multi block styrene copolymer and are therefore of limited interest due to poor fulfilment of properties desirable in adhesives.

5 US Patent No. 4,022,723 discloses a pressure sensitive adhesive using a terpolymer of styrene, isobutylene and beta-pinene. The terpolymer is a random copolymer of low molecular weight of from 1500 to 7000. It is claimed to be suitable as a tackifier resin.

10 US Patent No. 3,908,658 discloses a seal and appliance system for ostomy patients. A low molecular weight styrene-isobutylene copolymer is used together with an ethylene-vinyl acetate copolymer and mineral oil. The styrene-isobutylene copolymer used is a random copolymer, supplied by Velsico under the trade name Klyrvel 90 comprising 90% styrene and 10 % isobutylene. These copolymers are known to have molecular weight of 6000 to 12000. The high content of  
15 styrene indicates that it is a hard material lacking in flexibility and cannot be very elastic.

JP Patent No. 61235451 discloses the use of liquid styrene-isobutylene copolymer as a softener for Styrene Butadiene Compounds (SBC) in hydrophobic ad-  
20 hesives. Diblock copolymers do not provide physical cross-linking and therefore are not elastomers. This polymer will require addition of cohesion strengtheners, such as elastomers SIS or styrene-isobutylene-styrene (SIBS) for obtaining a good adhesive formulation.

25 Now new polymerisation methods have been developed and enabled the production of styrene-isobutylene-styrene tri- or higher block copolymers, including star copolymers, having various molecular weights and styrene content.

• The use of these polymers is disclosed in JP patent application No. 2002-  
30 161186, which discloses SIBS block copolymers, which can be used in combination with other cross-linkable styrene block copolymers for improved flexibility, mechanical strength, gas-barrier properties and mouldability, suitable for sealing

material requiring good permanent compression properties. JP patent application No. 2002-161186 is silent with respect to the use of such copolymers in adhesive compositions.

- 5 It has been surprisingly found that SIBS can be used for formulating soft adhesive formulations without compromising the tensile strength. It has also been found that SIBS offers superior softness and barrier properties. The polyisobutylene block, being a saturated chain, provides superior resistance against yellowing and deterioration. It has been found that the polyisobutylene block imparts  
10 new properties to the adhesive composition rendering the adhesive more suitable for use as skin adhesive.

- It has surprisingly been found that it is possible to control the properties of the adhesive composition by controlling the content of PIB in the soft domain of SIBS  
15 by addition of PIB homo-polymers. There is good compatibility between the soft segment of the block copolymer and the homo-polymer. By such combinations improved properties may be obtained, which have only been partially achievable by SIS copolymers or polyisobutylene homo-polymers or combinations thereof.
- 20 It has been surprisingly found that with a combination of SIBS copolymer and PIB homo-polymer, it is possible to prepare an adhesive composition for skin application without the use of conventional plasticizers normally used in connection with styrene copolymers in adhesive compositions.

## 25 SUMMARY OF THE INVENTION

- The invention relates to adhesive compositions comprising a rubbery elastomeric matrix comprising a block-copolymer and a homo-polymer wherein the block-copolymer is a three or multi-block copolymer comprising a monoalkenyl arene component and an unsaturated component.

- 30 Furthermore, the invention relates to the use of such adhesive compositions for the preparation of a wound dressing or an adhesive wafer for an ostomy appli-



ance comprising an adhesive composition comprising a rubbery elastomeric matrix comprising a block-copolymer and a homo-polymer wherein the block-copolymer is a three or multi-block copolymer comprising a monoalkenyl arene component and an unsaturated component.

5

Still further, the invention relates to a wound dressing or an adhesive wafer for an ostomy appliance comprising an adhesive composition comprising a rubbery elastomeric matrix comprising a block-copolymer and a homo-polymer wherein the block-copolymer is a three or multi-block copolymer comprising a monoal-

10

kenyl arene component and an unsaturated component.

Yet further, the invention relates to methods for bandaging wounds or stomas using wound a wound dressing or an ostomy appliance comprising an adhesive wafer comprising an adhesive composition comprising a rubbery elastomeric ma-

15

trix comprising a block-copolymer and a homo-polymer wherein the block-copolymer is a three or multi-block copolymer comprising a monoalkenyl arene component and an unsaturated component.

#### **Detailed Description of the Present Invention**

20

The invention relates to an adhesive composition comprising a rubbery elastomeric matrix comprising a block-copolymer and a homo-polymer wherein the block-copolymer is a di, three, or multi-block copolymer comprising a monoalkenyl arene component and an unsaturated component, characterised in that the homo-polymer and the unsaturated component of the block-copolymer are made

25

from the same monomer.

It is preferred that the block-copolymer comprises blocks capable of forming a physically cross-linked matrix and that it is selected from block-copolymers comprising styrene and one or more olefins being suitable for use in medical adhe-

30

sives and more preferred a three or multi-block copolymer is a styrene-isobutylene-styrene copolymer giving desired properties as stated below.

In a further, preferred embodiment of the invention the rubbery elastomeric matrix comprises poly butylenes or isobutylene, preferably polyisobutylene.

5 Thus, it has been found that there is significantly reduced disruption of the physical cross-linking in the SIBS network from the PIB polymer as compared with a SIS network. This gives rise to increased cohesion in the adhesive.

10 Most surprisingly it has been found that the gel strength and deterioration resistance of the adhesive are improved Without limiting the invention to any specific theory it is believed that this may be because of better cohesion and compatibility.

15 Further it has surprisingly been found that adhesives formulated from SIBS block copolymer and PIB homo-polymer are much more transparent than equivalent formulations from SIS block copolymers and PIB homo-polymers. Without limiting the invention to any specific theory it is believed that this may be achieved due to complete compatibility of the soft domain in the block copolymer and because the PIB homo-polymer and that the domains clustering the Styrene blocks are too small to interfere with visible light. The more transparent appearance in medical  
20 adhesives can offer an aesthetic appeal and more confidence in use to patients.

Furthermore, because of the fully saturated nature of the polymer, when processed at high temperatures in medical adhesive formulations, there is a reduced tendency to yellowing as is seen in SIS adhesives. The yellowing in conventional  
25 formulations sometimes causes concern over the reproducibility and stability of the adhesive.

Suitable SIBS copolymers are such having a molecular weight Mw of from about 50,000 to about 150,000 or even up to 300,000 or 500,000. Suitable SIB copolymers are such having a molecular weight Mw of from about 30,000 to about  
30 150,000.

In a preferred embodiment the invention relates to an adhesive composition comprising from 1 to 70 % by weight of the composition of multi-block copolymer comprising a monoalkenyl arene component, up to 70% by weight of the composition of a second multi-block copolymer comprising a monoalkenyl arene component or of a homo-polymer, and from 5 to 60% by weight of the composition of one or more hydrocolloids.

Another preferred adhesive composition according to the invention comprises a substantially homogeneous mixture of 5 - 60 % of one or more rubbery components, 5 - 60 % of one or more hydrocolloids comprising one or more hydrocolloids, 0 - 25 % of one or more tackifier resins, 0 - 10 % of a plasticizer and 0 - 5 % pigment.

According to the invention it is foreseen that the adhesive composition comprising a three or multi-block copolymer in the form of a monoalkenyl arene component and an unsaturated component may be formulated according to several types of embodiments.

Thus, it is foreseen in a first embodiment of the invention that an adhesive composition may be based on an adhesive matrix constituted by a di, three, or multi-block copolymer in the form of a monoalkenyl arene component and an unsaturated component and a plasticizer for the monoalkenyl arene component. Such compositions may e.g. be based on a SIBS copolymer and a plasticizer such as DOA or DOP.

In a second embodiment of the invention an adhesive composition may be based on an adhesive matrix constituted by a di, three, or multi-block copolymer in the form of a monoalkenyl arene component and an unsaturated component and a second three or multi-block copolymer in the form of a monoalkenyl arene component and an unsaturated component and a homo-polymer made from the same monomer as the unsaturated component of the block-copolymer or a tacki-

- fier. Such compositions may e.g. be based on a SIBS copolymer, a second SIBS-copolymer or a SIS-copolymer, and a plasticizer such as DOA or DOP, or PIB.
- In a third and preferred embodiment of the invention an adhesive composition may be based on an adhesive matrix constituted by a di, three, or multi-block co-
- 5 polymer in the form of a monoalkenyl arene component and an unsaturated component and a homo-polymer made from the same monomer as the unsaturated component of the block-copolymer. Such compositions may e.g. be based on a SIBS copolymer a PIB.
- 10 A second three or multi-block copolymer in the form of a monoalkenyl arene component and an unsaturated component may be present in an amount up to 70% by weight of the total composition and suitably has a molecular weight  $M_w$  of from 1000 and up to about 300.000. A plasticizer may typically be present in an amount of from 0% to about 40% by weight of the total composition.
- 15 Paraffin oil may be present for providing softness to the adhesive composition and may be present in an amount from 5% to 25%, typically in an amount of about 15% by weight of the total composition.
- 20 The adhesive compositions of the invention are especially suitable for use for medical appliances such as ostomy bags, wound dressings, IV-fixations, adhesive surgical drapes, skin fixation of continence catheters, drains, breast prosthesis and monitoring devices. But the purpose of the adhesive of the invention also
- 25 relates to any other application associated to skin of any mammal. Further as secondary fields the adhesive will be suited for a wide number of industrial applications like for labels and stickers that should be wet or moisture sensitive due to for instance easy removal.
- 30 In a further embodiment of the invention the composition comprises water absorbing and water swelling hydrocolloid particles.

The presence of hydrocolloid particles being characterized by rapid swelling under influence of water may further improve moisture uptake and transmission. A disadvantage may be the lack of complete coherence at high loads of hydrocolloid particles of such adhesives when immersed in water over time but this may  
5 be compensated by a desired absorption capacity in some cases.

The addition of hydrocolloid particles will preferably be in the range of 5-60 % by weight but will not be limited to this range.

10 The total amount of hydrocolloids are typically 5-55% by weight of the total composition, more preferred 5-45% by weight, and preferably from 30 to 40% by weight of the total composition.

Such hydrocolloid particles are suitably naturally occurring hydrocolloids such as  
15 guar gum, locust bean gum, pectin, alginates, gelatin, xanthan or karaya gum, semi synthetic hydrocolloids such as cellulose derivatives, e.g. salts of carboxymethylcellulose, methylcellulose and hydroxypropyl methylcellulose, sodium starch glycollate and synthetic hydrocolloids such as polyvinyl pyrrolidone, polyvinyl alcohol, polyethylene glycol or certain polyacrylates.

20 It is often suitable to use a combination of two or more hydrocolloids such as a combination of pectin, gelatine and carboxymethylcellulose as the hydrocolloid component.

25 An especially preferred composition according to the invention comprises a mixture of polyisobutylene and SIBS and CMC.

In a further embodiment of the invention the composition comprises a tackifier resin.

30 A tackifying resin optionally used in accordance with the invention is preferably a hydrocarbon tackifier resin and is more preferred selected from the group com-

prising polymers and copolymers of cyclopentadiene, dicyclopentadiene, alpha-pinene or beta-pinene. A tackifier resin may be present in an amount of from 0 to 40% by weight of the total composition

- 5 The adhesive compositions of the invention may optionally comprise further components normally used in formulation of adhesive compositions such as pigments such as zinc oxide or titanium dioxide. Pigments may be present in amount up to about 5% and will typically be present in an amount of 2 - 4 %.
- 10 In a further aspect, the invention relates to an ostomy appliance for placing on the abdomen of a patient for use in collecting discharge of visceral contents, said appliance comprising an adhesive wafer having a surface constituted by an adhesive composition containing a rubbery elastomeric matrix and one or more water soluble or water swellable hydrocolloids, said adhesive composition comprising
- 15 ing a substantially homogeneous mixture of 25 - 60 % of one or more polybutenes, 3 - 35% of one or more styrene copolymers, and 20 - 60% of one or more hydrocolloids.

- An ostomy appliance according to the invention may be an open or a closed appliance suitable for use in connection with a colostomy, an ileostomy or a urostomy. It may be a one-piece appliance or a body side member or faceplate forming part of a two-piece appliance comprising the body side ostomy member and a separate collection bag. A separate collection bag may be attached to the body side member in any convenient manner known per se, e.g. via a coupling
- 20 ring or by a flange covered with an adhesive.
- 25

- An ostomy appliance according to the invention may be made from materials conventionally used for the preparation of ostomy appliances in a manner known per se in the field.

- 30 In a preferred embodiment of the invention for use in an ostomy appliance, the adhesive composition the adhesive component in a "Swiss roll" adhesive of the

kind disclosed in WO 89/05619, the other, more absorbing, component e.g. comprising a mixture of a suitable adhesive, preferably a PIB-based and a hydrocolloid.

- 5 In a still further aspect, the invention relates to a wound dressing for covering e.g. a wound, an abrasion, a blister, a crack or a corn comprising an adhesive composition containing an adhesive composition containing a rubbery elastomeric matrix and one or more water soluble or water swellable hydrocolloids, said adhesive composition comprising a substantially homogeneous mixture of 25 - 60 %  
 10 of one or more polybutenes, 3 - 35% of one or more styrene copolymers, and 20 - 60% of one or more hydrocolloids and a top layer or film.

- A water impervious layer or film may be of any suitable material known per se for use in the preparation of wound dressings e.g. a foam, a non-woven layer or a  
 15 polyurethane, polyethylene, polyester or polyamide film.

- A water impervious layer or film is preferably a low-friction flexible polymer film reducing the risk of unwanted stress in the area of the crack impeding the healing of a crack on a very exposed site.

- 20 A suitable material for use as a water impervious film is a polyurethane material. A preferred low friction film material is disclosed in US patent No. 5,643,187. A preferred thickness of this film is below 20 microns, more preferred about 12-18 microns, resulting in a significant decrease of the modulus as compared to a film  
 25 that is normally used when preparing medical dressings giving an improved stretchability and adaptability of the dressing.

- In a further aspect, the invention relates to a method for bandaging a stoma on the abdomen of a patient for use in collecting discharge of visceral contents, said  
 30 method comprising locating the stoma and an ostomy appliance comprising an adhesive wafer having a surface constituted by an adhesive composition according to the invention, optionally providing a hole in the adhesive wafer correspond-

ing to the size and shape of the stoma and placing the adhesive wafer on the abdomen in sealing contact with the skin and the stoma.

5 In a still further aspect, the invention relates to a method for bandaging a wound on the skin of a patient, said method comprising locating the wound and a wound dressing comprising an adhesive composition having a surface constituted by an adhesive composition according the invention, and placing the wound dressing on the skin of the patient so as to cover the wound and the skin in a zone along the perimeter of the wound.

10

#### **Description of the Preferred Embodiments**

The invention is now explained more in detail with reference to the below working examples elucidating preferred embodiments of the invention.

#### **15 MATERIALS AND METHODS**

SIBSTAR 073T: Styrene-isobutylene-styrene block copolymer from Kaneka Corporation having a molecular weight  $M_w = 65,000$ .

20 SIBSTAR 102T: Styrene-isobutylene-styrene block copolymer from Kaneka Corporation having a molecular weight  $M_w = 100,000$ .

25 PIB: Polyisobutylene available under the trademark Vistanex from Exxon Chemical Co. as grade LM-MH.

Kraton D1161: Styrene-isoprene-styrene (SIS) copolymer from Kraton Polymers UK Ltd having a molecular weight  $M_w$  of 212,000-260,000 (GPC) and a content of diblock 15-25%.

30 Arkon P90: A saturated alicyclic hydrocarbon resin from Arakawa Chemical Industries having a molecular weight 570 and a softening point of 90°C.

Paraffin oil: PL 500 from Parafluid Mineral Oil



CMC: Sodium carboxymethylcellulose available from Hercules under the trade name Blanose 9H4XF or from Akzo under the trade mark Akucell® AF2881

Diocetyl adipate, a plasticizer from International Speciality Chemicals Ltd.

Diocetyl phthalate, a plasticizer from International Speciality Chemicals Ltd

A Z mixer Type LKB 025 from Herman-Linden was used.

**Example 1 and Comparative Example 1**  
Clarity of film

The clarity of a film of a polymer used according to the invention was compared to the clearness of a film of a polymer composition according to the state of the art having the compositions stated in the below Table 1 were compared visually. The composition according to Example 1 is according to the invention and the composition according to Comparative Example 1 is according to the state of the art.

**Table 1**

Ingredient in percent by weight	Example No.	
	1	Comp 1
SIBSTAR 073T	50	
SIS		50
PIB	50	50
Total	100	100

100 grams of Kraton® D1161 or SIBSTAR 073T was added to a Z mixer at 160 °C and softened for 5 minutes. Then 100 grams of PIB was added and mixing was continued at 150 °C and 50 mbar until the blend was homogeneous.

While still hot and soft, the resulting dough-like mass was then removed from the mixer and formed into a film material having a thickness of approximately 0.2 mm

by compression moulding the adhesive mass at approximately 110 °C and 100 Bar between two sheets of silicone release paper.

The appearance of the film of Example 1 was clear whereas the appearance of the film of Comparative Example 1 was opaque.

#### Examples 2-4 and Comparative Examples 2-3

Determination of water absorption, erosion and gel strength for adhesive compositions according to the invention and adhesive compositions according to the state of the art.

Compositions according to Examples 2-4 are according to the invention and the composition according to Comparative Examples 2 and 3 are according to the state of the art and are stated in the below table 2.

**Table 2**

Ingredient in percent by weight	Example No.				
	2	Comp 2	Comp 3	3	4
SIBSTAR 102T				25	18
SIBSTAR 073T	25				
SIS		25	25		
PIB	25	25	40	40	47
Paraffin Oil	15	15			
CMC	35	35	35	35	35
Total	100	100	100	100	100

100 grams of Kraton® D1161, SIBSTAR 102T or SIBSTAR 073T was used and the amounts of other ingredients used correspond to the composition stated in Table 2.

Equal amounts of Kraton® D1161 SIBSTAR 102T or SIBSTAR 073T and Vistanex® LM-MH were mixed in a Z Mixer for 20 minutes at 160 °C under a vacuum

of 100 mbar. Then, the vacuum was released, the mixing was continued at 160 °C for 10 minutes and the remains of Vistanex® LM-MH, and PL 500 were added and mixed for 10 minutes each. Then, the mixture was cooled to 90°C. Finally, CMC was added at a temperature of 90 °C under a vacuum of 100 mbar and  
5 mixed for 10 minutes.

While still hot and soft, the resulting dough-like mass was then removed from the mixer and formed into a sheet stock material having a thickness of approximately 1 mm by compression moulding the adhesive mass at approximately 90 °C and  
10 100 Bar between two sheets of silicone release paper. The resultant flat plate was cut into the desired shapes.

**Determination of water absorption.**

Pieces of adhesive of 1x25x25 mm were immersed in 9% NaCl demineralised  
15 water at 37°C and removed and weighed after 30, 60, 90, 120, 240, and 1440 hours. The percentage change in weight is recorded.

A comparison of SIBS and SIS based compositions (Example 2 with comparative example 2, and example 3 with comparative example 3) shows that similar absorption rates are achieved initially but on prolonged immersion, the absorption of  
20 compositions comprising SIBS slows down. This is believed to be due to increased cohesion or barrier properties of SIBS compositions, preventing a continuing deteriorating process due of increased water content.

25 The results appear from the below table 3.

**Table 3**

Weight of specimen in percent of initial weight after immersion

Time (min.)	Example				
	2	Comp 2	Comp 3	3	4
30	133	137	112	110	107
60	178	199	140	142	151
90	211	257	164	153	188
120	234	295	185	168	215
240	316	446	261	222	311
1440	538	869	723	481	793

**5 Determination of deterioration.**

- A disk of the adhesive having a thickness of 1mm, an outer diameter of 50 mm and a hole of diameter of 15 mm was coated on the top surface with an impermeable film of LDPE. The exposed surface was attached to the surface of a petri dish. The adhesive and dish were left at 37°C for 24hrs. Then the dish was filled with 9% NaCl demineralised water. The whole adhesive specimen was covered by water. The dish was then covered with a plastic sheet and left at 37°C for 24 hrs. The diameters of the inner hole and outer edge were then measured.

- Deterioration was shown by an inner diameter less than 15mm, and an outer diameter of greater than 50mm.

The results appear from the below table 4.

**Table 4**

Determination of deterioration. Dimension of hole and outer diameter of disk in millimetres

Example	2	Comp 2	Comp 3	3	4
Diameter hole	12	11	11	12	12
Diameter disk	56	59	56	52	55

- 5 The compositions comprising SIBS show improved resistance against deterioration over state of the art compositions comprising SIS. This is especially useful in applications where larger amounts of fluid are to be handled, e.g. in connection with ostomy appliances and wound dressings for exuding wounds. Thus, compositions comprising SIBS would provide further safety and wear time.

10

#### **Determination of gel strength.**

- A disc of the adhesive at 1mm thickness with a diameter of 50mm was attached to the surface of a petri dish and the other surface of the disk was exposed. The adhesive and dish were left at 37°C for 24hrs. Then, the dish was filled with 9% NaCl demineralised water. The whole adhesive specimen was covered by water. The dish was then covered with a plastic sheet then left at 37°C for 24 hrs. The increase of diameters of the discs, appearance of the discs was evaluated visually and rated "-" for no change and "u" for change of shape, surface smoothness and cohesive strength by scratching with a finger were noted. The last two parameters were given an arbitrary rating of 1 to 5, with 1 being the best.

20

- The compositions comprising SIBS showed overall improved gel strength. This is especially useful in applications where larger amounts of fluid are to be handled. Compositions comprising SIBS would provide further safety and wear time as above.

25

The results appear from the below table 5.

**Table 5**

Example	2	Comp 2	Comp 3	3	4
Increase of diameter in %	0	52	20	0	12
Disc Appearance	3	3	3	3	2
Smoothness	—	—	—	—	—
Strength	2	1.5	2	1.5	2

**Claims**

1. An adhesive composition comprising a rubbery elastomeric matrix comprising a block-copolymer and a homo-polymer wherein the block-copolymer is a di,  
5 three, or multi-block copolymer comprising a monoalkenyl arene component and an unsaturated component, characterised in that the homopolymer and the unsaturated component of the block-copolymer are made from the same monomer.
2. An adhesive composition as claimed in claim 1, characterised in that the three  
10 or multi-block copolymer is a styrene-isobutylene-styrene copolymer
3. An adhesive composition as claimed in claim 1 or 2, characterised in that the homo-polymer is polyisobutylene.
- 15 4. An adhesive composition as claimed in any of claims 1-3, characterised in that the composition comprises one or more water-soluble or water swellable hydrocolloids.
- 20 5. An adhesive composition as claimed in any of claims 1-4, characterised in that the composition comprises a tackifier resin.
6. An adhesive composition as claimed in any of claims 1-5, characterised in that it comprises from 1 to 70 % by weight of the composition of multi-block copolymer comprising a monoalkenyl arene component, up to 70% by weight of the composition of homo-polymer, and from 5 to 60% by weight of the composition of one or  
25 more hydrocolloids.
7. An ostomy appliance comprising an adhesive wafer comprising an adhesive composition according to any of claims 1 to 6.
- 30 8. A wound dressing comprising an adhesive composition according to any of claims 1 to 6.

9. A method for bandaging a stoma on the abdomen of a patient for use in collecting discharge of visceral contents, said method comprising locating the stoma and an ostomy appliance comprising an adhesive wafer having a surface constituted by an adhesive composition according to any of claims 1-6, optionally providing a hole in the adhesive wafer corresponding to the size and shape of the stoma and placing the adhesive wafer on the abdomen in sealing contact with the skin and the stoma.
10. A method for bandaging a wound on the skin of a patient, said method comprising locating the wound and a wound dressing comprising an adhesive composition having a surface constituted by an adhesive composition according to any of claims 1-6, and placing the wound dressing on the skin of the patient so as to cover the wound and the skin in a zone along the perimeter of the wound.

15



**Abstract****An Adhesive Composition and Use of Such Composition**

5

An adhesive composition comprising a rubbery elastomeric matrix comprising a block-copolymer and a homo-polymer wherein the block-copolymer is a di, three, or multi-block copolymer comprising a monoalkenyl arene component and an unsaturated component, characterised in that the homo-polymer and the unsaturated component of the block-copolymer are made from the same monomer provides better performance as adhesive for use on human skin and overcomes drawbacks of state of the art adhesives.

10